FEB 1 7 2000

K994414

510 (k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Identification: Second set of InstaCheck® Multi-Drug Screen Panels

Description: One-step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of THC, Cocaine, PCP, Morphine, Methamphetamine, Amphetamine, Barbiturates and Benzodiazepines in urine.

Name of Manufacturer:

Forefront Diagnostics, Inc.
23561 Ridge Route Dr. Suite D
Laguna Hills, CA 92653

Intended Use: The Forefront Diagnostics InstaCheck® Multi-Drug Screen Panels are *in vitro* screen tests for the rapid detection of target drugs/metabolites in urine. The cut-off concentration for these tests is as follows: THC: 50ng/ml, Cocaine: 300 ng/ml, PCP: 25 ng/ml, Barbiturates: 300 ng/ml, Benzodiazepines: 300 ng/ml, Morphine: 300 and 2000 ng/ml and Methamphetamine: 1000 ng/ml. The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

Technology: The InstaCheck® Multi-Drug Screen Panels, like multi-drug tests from other manufacturers such as Roche, American Biotech Inc, etc. as well as currently marketed Drug Screen Single Test "predicate" devices, qualitatively measure the presence of target drugs or their metabolites by visual color sandwich one step immunoassay technology. Our currently marketed InstaCheck® Drug Screen Single Test Panels are used for substantial equivalence predicate kit because other manufacturers' multi-drug tests use different drug combinations compared with our InstaCheck® Multi-Drug Screen Panels. All of these products are based on the same immunochemical principle of recognition and formation of specific antibody / target drug / antibody / complexes.

Performance: The product performance characteristics of InstaCheck® Multi-Drug Screen Panels were evaluated in a blind-labeled spiked control study and in a blind-labeled clinical specimen correlation study. The results of these studies demonstrate the InstaCheck® Multi-Drug Screen Panels to be substantially equivalent to the performance characteristics of the InstaCheck® Drug Screen Single Test panels, which have received 510(k) approvals. Correlation studies, using clinical specimens, produced a >97% correlation when compared to the predicate kit and GC/MS methodology. Clinical site studies, performed at Forefront Diagnostics, Inc and three independent laboratories, were also performed. The results of this study demonstrated that the InstaCheck® Multi-Drug Screen Panels can be performed by professional and laboratory personnel to obtain a visual, qualitative, rapid detection of drugs of abuse and its metabolite with an accuracy >98%.

Conclusion: For the reasons mentioned above, it may be concluded that InstaCheck® Multi-Drug Screen Panels are substantially equivalent to the InstaCheck® Drug Screen Single Test Panels presently distributed commercially.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 7 2000

Mr. Feng Lee
Manager of Regulatory Affairs
Forefront Diagnostics, Inc.
23561 Ridge Route Drive
Suite D
Laguna Hills, California 92653

Re: K994414
Trade Name: InstaCheck® Multi-Drug Screen Panels
Regulatory Class: II
Product Code: DKZ, LAF, DIO, DJG, LDJ, DIS, JXM, LCM
Dated: December 27, 1999
Received: December 29, 1999

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K994414

Device Name: InstaCheck® Multi-Drug Screen Panel THC/COC, MOR 2000/MET Test

Indications For Use:

The Forefront Diagnostics InstaCheck® Multi-Drug Screen Panel THC/COC/MOR 2000/MET Test is an *in vitro* screen test for the rapid detection of 11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid, Cocaine and its metabolite - Benzoylecgonine, Morphine and Methamphetamine in human urine at the following concentrations.

THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**
MOR	**Morphine**	**2000 ng/ml**
MET	**Methamphetamine**	**1000 ng/ml**

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994414

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): K994414

Device Name: InstaCheck® Multi-Drug Screen Panel THC/COC/PCP/MOR 2000/MET Test

Indications For Use:

The Forefront Diagnostics InstaCheck® Multi-Drug Screen Panel THC/COC/PCP, MOR 2000/MET Test is an *in vitro* screen test for the rapid detection of 11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid, Cocaine and its metabolite - Benzoylecgonine, PCP, Morphine and Methamphetamine in human urine at the following concentrations:

THC	**11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid**	**50 ng/ml**
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Device Name: InstaCheck® Multi-Drug Screen Panel THC/COC/MOR 2000/MET/AMP Test

Indications For Use:

The Forefront Diagnostics InstaCheck® Multi-Drug Screen Panel THC/COC, MOR 2000/MET, AMP Test is an *in vitro* screen test for the rapid detection of 11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid, Cocaine and its metabolite - Benzoylecgonine, Morphine, Methamphetamine and Amphetamine in human urine at the following concentrations.

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Indications For Use:

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